DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 2004N–0194]

Definition of Primary Mode of Action of a Combination Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending until August 20, 2004, the comment period on the primary mode of action proposed rule that appeared in the **Federal Register** of May 7, 2004 (69 FR 25527). In the primary mode of action proposed rule, the agency states its intentions to amend the product jurisdiction regulations to define ''mode of action'' and ''primary mode of action'' (PMOA). Along with these definitions, the proposed rule sets forth an algorithm the agency would use to assign combination products to an agency component for regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product. Finally, the proposed rule would also require a sponsor to base its recommendation of the agency component with primary jurisdiction for regulatory oversight of its combination product on the PMOA definition and, if appropriate, the assignment algorithm. The proposed rule is intended to promote the public health by codifying the agency's criteria for the assignment of combination products in transparent, consistent, and predictable terms.

DATES: Submit written or electronic comments no later than August 20, 2004.

ADDRESSES: You may submit comments, identified by Docket 2004N–0194, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0194 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. 2004N–0194 or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leigh Hayes, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION: FDA issued this proposed rule with an opportunity for public comment during a 60-day time period beginning May 7, 2004. On May 18, 2004, FDA received a request from the Advanced Medical Technology Association (AdvaMed) to extend the comment period for an additional 60 days for Docket No. 2004N–0194. According to AdvaMed, the Association needs additional time to advise their members about the proposed rule, and to collect and organize their members' input regarding the proposed rule.

Comments

In response to the request from AdvaMed, FDA is extending the comment period an additional 45 days to close on August 20, 2004. This extension will provide the public with a total of 105 days to submit comments. To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposed rule by August 20, 2004. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper

copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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